## REMARKS

No claims have been amended by this paper, and claims 15-21 have been withdrawn from consideration. Claims 1-23 are pending.

Applicant is grateful for the opportunity to chat with the examiner over the telephone on November 15, 2007. Applicant's response here attempts to address the examiner's points raised in the conference and in the final Office action.

Claims 1-4, and 9 were rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over Beard (U.S. Published Patent Application No. 2002/0005047). Claims 7, 8, and 10-14 were rejected under 35 U.S.C. § 103(a) as obvious over Beard. Claims 5, 22, and 23 were rejected under 35 U.S.C. § 103(a) as obvious over Beard and in view of Ishibe (U.S. Patent No. 5,230,348). Claim 6 was rejected under 35 U.S.C. § 103(a) as obvious over Beard alone or in view of either Iwai et al. (U.S. Patent No. 5,334,294) or Wang et al. (U.S. Patent No. 6,375,826). These rejections are respectfully traversed. Applicant respectfully disagrees with any grounds for rejection not specifically addressed below.

Applicant relies here on the response propounded previously, namely, that since the references do not teach or suggest the claimed process limitations (e.g., ingot A(f) range, percent cold work, level of impurities, the final cold work step of less than 30%, etc.), none of the claims is anticipated by the cited references; and since not all limitations are taught or suggested by the cited references, the examiner has not established *prima facie* obviousness.

The examiner asserts that the burden has shifted to applicant to show that steps associated with the claims result in a product materially different from that disclosed in Beard. In response, applicant submits herewith for the examiner's consideration a Rule 1.132 declaration of a person skilled in the art who has taken over the project that the co-

inventors were working on that led to the patent application. The declarant is Craig Mar, Principal Engineer at assignee Paracor Medical, Inc.

On page 2 of the final Office action, the examiner in paragraph 2 states that "properties or conditions of the claimed material at some point in the past, but not necessarily present in the claimed material, will be given little weight in determining patentability of the instant claims." Applicant respectfully points out that these "past" process limitations such as the ingot A(f) temperature that characterize the wire processing cannot and should not be ignored.

Specifically, paragraph 7 of the Mar declaration explains that:

> the past processing history of the material does affect the later crystal structure, and crystal distribution and the impurity distribution in the material. This would in turn affect the A(f). Indeed, if the ingot A(f) temperature were not within the specified range (as defined in the claims), or the lower amount of cold work or other process steps not followed, then the final wire would not have the high fatigue properties as described in applicant's patent application. Thus, ***properties or conditions in the past processing are present in the current condition or property of the nitinol material*** (emphasis added).

On page 3 of the examiner's Office action, the examiner contends that applicant must carry the burden of showing that any process steps associated with the claims result in a product materially different from that disclosed from the cited art. In paragraph 9 of the Mar declaration, the declarant avers that the Beard wire is analogous to the "standard nitinol wires" referenced in paragraph [0014] of applicant's specification, which wires had failures at 16,560 cycles. On the other hand, the present invention nitinol wires have a fatigue life of over 380,000,000 cycles to failure under the same testing conditions as the analogous Beard wire. The dramatic improvement in fatigue lift demonstrates the material difference between the present invention wire and the Beard wire.

This is further an unobvious difference between the present invention claimed nitinol wire versus the Beard wire. M.P.E.P. 2113. Paragraph 10 of the Mar declaration

explains that not only are the requirements for the implantable device much greater than for a non-implantable medical device (and still greater yet as compared to cosmetic jewelry), but many of the requirements could only be ascertained by trial and error or hard experience. Therefore, it is the opinion of a person skilled in the art that given the teaching of jewelry wire in Beard, that a person skilled in the art could then extrapolate and create a wire, ribbon, sheet, or tube of the claimed invention and make it suitable for an implantable medical device would be a nearly impossible endeavor.

Finally, paragraph 9 of the Mar declaration states "that our fatigue life results are unexpectedly greater than the classical (Beard) treatment, and our claimed fatigue failure curve (plot of stress S versus N cycles to failure) does not behave in the classical manner." The fact that the processing worked in an unexpected and fruitful manner supports the conclusion that the present invention is not obvious to those skilled in the art. *See KSR Int'l Co. v. Teleflex Inc. et al.*, No. 04-1350, slip op. at 12 (S. Ct. April 30, 2007).

Hence, applicant believes that it has met the burden of showing that its product-by-process claimed nitinol wire, ribbon, sheet, or tubing is materially different from and unobvious in view of the Beard nitinol wire. Further, the past process conditions or properties set forth in the claims cannot be ignored because they are present in the current product. As such, all claims are distinguishable over and are not obvious in view of the cited references individually or in combination.

In view of the foregoing, all claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited.

Respectfully submitted,

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